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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/522,554 03/10/00 ROSSI

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EXAMINER

CEPERLEY, M

ART UNIT

PAPER NUMBER

1641
DATE MAILED:

10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/522,554

Applicant(s)

ROSSI, FRANCIS M.

Examiner

Mary E. (Molly) Ceperley

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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1. In accordance with the duty to disclose, applicant is requested to provide an Information Disclosure Statement which cites and provides copies of the most relevant prior art. At a minimum, applicant is requested to provide copies of the prior art which is cited in the specification.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12 are rejected under 35 USC 112, first and second paragraphs, as being based on a specification which does not contain an adequate written description of the invention and as being indefinite for the following reasons.

a) The following terms which are used in the claims are not specifically defined in the specification: "affinity anchors", "array", "molecules of interest", and "cleavable linker molecule". Although *example definitions* are provided for some of these terms (see for example, page 11, lines 16-18), the specification provides no definitive characterization or functional description of these terms. Consequently, the exact scope of the claims cannot be determined. It is noted that the term "electrodes" is specifically defined at page 9, lines 19-29 of the specification.

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b) The specification does not provide an adequate enabling **written description** of the invention. From a reading of the specification, one skilled in the art cannot ascertain where the inventive concept lies. As set forth in the prior art rejections below, the invention, **as claimed in instant claim 1**, is readable on a conventional competitive immunoassay, an indirect ELISA and a standard sandwich ELISA (see the Faix and Voller et al references below).

c) It is unclear where the "at least about 1000 electrodes" of claim 12 are located relative to the "array" of claim 9.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-4 and 8-11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of Faix (Immunoassay Automation: A Practical Guide, Chapter 14, Academic Press,, Inc. ((1992)) or Voller et al (Manual of Clinical Laboratory Immunology, Chapter 17, Amer. Soc. For Microbiology (1986)). Each of the references describes the immobilization of a plurality of first members of a specific binding pair onto an array ("immobilizing a plurality of affinity anchors onto the array"), the contacting of the first members of the specific binding pair with the corresponding second member of the specific binding pair ("preparing a plurality of molecules of interest having affinity for the anchors" and "contacting the molecules of interest with the array") and washing the resulting array ("washing the array to remove unbound molecules of interest"). These methods anticipate the method of instant claim 1 and the products of claims 8 and 9. See Faix, Figure 5 and Voller et al, page 108, Indirect microplate ELISA and Sandwich ELISA for Measurement of Proteins.

The features of the dependent claims are either specifically described by the references (e.g. the "affinity anchor" being an "antibody") or constitute obvious variations in parameters which are routinely modified in the art (e.g. choice of specific binding pair members) and which have not been described as critical to the practice of the invention.

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8. Claims 1-12 are rejected under 35 U.S.C. 102(b)/(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of Montgomery (U.S. 6,280,595), Ackley et al (U.S. 6,254,827), Heller et al (U.S. 5,632,957), Ribí et al (U.S. 5,571,568), or Hafeman et al (U.S. 4,591,550).

Each of the references describes a method of attaching members of a specific binding pair to an "array" of electrodes to produce a product as described in instant claims 7 and 12 and as encompassed by the remaining claims which do not specifically describe the use of "electrodes" but which encompass their use ("comprising the following steps"). These methods and products anticipate those of the instant claims. See Montgomery: col. 5, line 30 – col. 6, line 46; col. 18, line 31 – col. 19, line 18 (cleavable linker); col. 26, lines 50-52 (washing step); Ackley et al: col. 6, lines 3-41; Heller et al: col. 4, line 60 – col. 5, line 17; col. 17, lines 38-45; Ribí et al: col. 3, line 18 – col. 4, line 15; Hafeman et al: col. 3, line 27 – col. 5, line 45.

The features of the dependent claims are either specifically described by the references (e.g. see the cleavable linker and washing step of Montgomery) or constitute obvious variations in parameters which are routinely modified in the art (e.g. choice of specific binding pair (avidin-biotin, antigen-antibody, etc.) or washing step to remove unbound material) and which have not been described as critical to the practice of the invention.


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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7230.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

September 30, 2001


Mary E. Ceperley
Primary Examiner
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